

Department of State Health Services
Council Agenda Memo for State Health Services Council
April 3, 2013

Agenda Item Title: Repeal of a rule and a new rule concerning registration of radiation machine use and services

Agenda Number: 6.f.

Recommended Council Action:

☐ For Discussion Only

☒ For Discussion and Action by the Council

Background: The Radiation Control Program in the Division for Regulatory Services protects and promotes the physical and environmental health of Texas citizens. The program includes licensing, registration, inspection, enforcement, and emergency response functions for the use of radioactive material and radiation machines. The program regulates approximately 1,600 licensees and 16,000 registrants.

The program routinely monitors complaints received and resolved, the number of new and renewed registrations, the number of disciplinary actions taken, and violation trends. The number of complaints received, enforcement actions, inspections performed, and registration actions are monitored on a quarterly basis.

In the last quarter, approximately 1,700 inspections of radiation machines were performed resulting in approximately 250 disciplinary actions.

The program charges fees for issuing licenses and registration and is entirely fee funded.

Summary: The purpose of the repeal and new rule is to ensure continued enhanced protection of the public, patients, workers, and the environment from unnecessary exposure to radiation by providing rules that are clear and specific and requiring radiation machines to be properly registered with DSHS.

The proposed changes correct references; update terminology; and update names of forms and professional boards. The rule changes clarify that service providers can perform equipment performance evaluations for dental and veterinary radiation machines; clarify language to differentiate between physician and certified physician; and clarify that an entity under the jurisdiction of the federal government is not held to the requirements of this rule. The proposed changes exempt transmission microscopes and require lasers, laser services, laser hair removal facilities, laser hair removal training programs, and laser hair removal individuals to submit separate applications for registration.

The proposal will permit therapeutic radiation machines operating at or above 1 MeV to be energized for purposes of installation and acceptance testing before receiving a certificate of registration; require a person to apply for and receive a registration for electronic brachytherapy devices before using on humans; and require a person that performs healing arts screening programs to ensure proper follow-up care. The proposed changes update the education and training requirements for persons performing radiation machine assembly, installation or repair; and clarify that linear accelerators and healing arts screening procedures shall be registered prior to human use.

In addition, the proposal will require a person providing radiation machine services to ensure that the person transferring or having a radiation machine installed has a completed application or a current certificate of registration. The proposed changes require the registrant to notify DSHS within 30 days of a new use location to be added to the certificate of registration; require providers of radiation machines to maintain a log of machines provided; and prohibit demonstration of radiation machines on humans unless by or under the direction of a practitioner.

The proposal will require the radiation safety officer to review operating and safety procedures at intervals not to exceed 12 months; require an equipment performance evaluation be performed on radiation machines within 30 days of installation or re-installation; and clarify the duties of the physicist when supervising a non-physicist. The proposed changes allow the radiation safety officer, owner, or an individual authorized to act on behalf of the registrant to sign the request for termination of the certificate of registration. The rule changes require research using radiation machines on humans be approved by an Investigational Review Board; extend the interval for reciprocity requests from one year to two years; and require the retention of records for training and experience of service providers to until termination of registration or five years after the individual terminates employment.

In addition, this rule complies with the four-year review of agency rules in Government Code, Section 2001.039.

Key Health Measures: The program collects and analyzes data related to the number of licensed and registered facilities meeting state and federal requirements, the number of complaint investigations conducted, and the number of violations or facilities referred for enforcement action. Program staff has evaluated the effectiveness of the current rule by collecting and reviewing these performance measures and the findings were used to identify areas where rule revisions and clarifications were needed.

The effectiveness of the program and new rule will be indicated by an increase in the number of applications and related correspondence submitted and approved within the required timeframes. This will ensure radiation machines are properly registered with DSHS resulting in a more efficient administrative program. In addition, facilities complying with the new administrative and machine use rule requirements will result in a decrease in the number of violations or facilities that are referred for enforcement action.

Summary of Input from Stakeholder Groups: The draft rule has undergone five revisions with stakeholder input throughout the process. The draft rules were posted on the Radiation Control web site. (www.dshs.state.tx.us/radiation/draft/shtm). Stakeholders and appropriate DSHS staff were notified of the draft rule and given the opportunity to comment and feedback was received from individuals and groups.

Two stakeholders suggested revising the requirement to perform an equipment performance evaluation on all radiation machines at the time of installation or reinstallation to 30 days from the installation of the machines. DSHS included clarifying language to address this comment. Five stakeholders inquired if the facility could continue to use a single registration for a centralized office with multiple machine use locations. Wording was added to the rule to clarify the intent that additional sub-sites may be added under one registration. Eleven comments were received regarding the conditions when a non-physicist collects entrance exposure data. DSHS added language to address this comment.

The Texas Radiation Advisory Board reviewed the proposed rule at their December 7, 2012, meeting and recommended that the proposed rule be forwarded to the State Health Services Council for consideration.

Proposed Motion:

Motion to recommend HHSC approval for publication of rules contained in agenda item #6.f.

Approved by Assistant Commissioner/Director:	Kathryn C. Perkins, R.N., M.B.A.	Date:	1/30/2013
Presenter:	Barbara J. Taylor, Manager, Radiation Group	Program:	Policy/Standards Quality Assurance Unit
Approved by CCEA:	Carolyn Bivens	Date:	1/30/2013

TITLE 25 HEALTH SERVICES
Part 1. DEPARTMENT OF STATE HEALTH SERVICES
Chapter 289. Radiation Control
Subchapter E. Registration Regulations
New §289.226
Repeal §289.226

Proposed Preamble

The Executive Commissioner of Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes the repeal of §289.226 and new §289.226 concerning the registration of radiation machine use and services.

BACKGROUND AND PURPOSE

This proposal undertakes to correct rule citation references; update terminology to be consistent with current technology; update form names and names of professional boards; clarify that radiation machines used in veterinary medicine are required to have equipment performance evaluations performed; clarify language to differentiate between physician and certified physician; clarify that an entity under the jurisdiction of the federal government is not held to the requirements of this section; add transmission microscopes to the exemption section; and clarify that lasers, laser services, laser hair removal facilities, laser hair removal training programs, and laser hair removal individuals are required to submit separate applications for registration.

The proposal will permit therapeutic radiation machines operating at or above 1 MeV to be energized for purposes of installation and acceptance testing before receiving a certificate of registration; add requirements to apply for and receive a registration for electronic brachytherapy devices; require healing arts screening programs to determine a method for patients to select a physician for follow-up for those who do not have a physician; update the minimum education and training requirements for persons performing radiation machine assembly, installation or repair; and clarify that linear accelerators and healing arts screening procedures shall be registered prior to human use.

In addition, the proposal will clarify that a person providing radiation machine services shall ensure that the person transferring, or having a radiation machine installed, shall have evidence of a completed application for registration or be in possession of a current certificate of registration; require the registrant to notify the department within 30 days of a new use location to be added to the certificate of registration; require providers of radiation machines to maintain a log of machines provided; and prohibit demonstration of radiation machines on humans unless by or under the direction of a practitioner.

The proposal will require the radiation safety officer to review operating and safety procedures at intervals not to exceed 12 months; require an equipment performance evaluation to be performed on radiation machines within 30 days of installation or re-installation; clarify the duties of the physicist when supervising a non-physicist that collects entrance exposure data; allow the option for the request for termination of the certificate of registration to be signed by the radiation safety

officer, owner, or an individual authorized to act on behalf of the registrant; require research using radiation machines on humans to be approved by an Investigational Review Board; extend the interval for reciprocity requests from 1 year to 2 years; and add language to require the retention of records for training and experience of service providers to until termination of registration or 5 years after the individual terminates employment.

In addition, this rule proposal satisfies the four year review of agency rules in Government Code, §2001.039, which requires that each state agency review every four years its rules and consider for readoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Section 289.226 has been reviewed in its entirety and the department has determined that the reasons for adopting new section 289.226 continue to exist.

SECTION-BY-SECTION SUMMARY

Throughout new §289.226 minor grammatical and typographical corrections are made, technical terminology is updated, rule reference citations are corrected and/or updated; and rule text extensively reorganized. In addition, form names and names of professional boards are updated.

Concerning §289.226(b)(11)(G), the phrase "and on machines used in veterinary medicine" is added to clarify that radiation services include completion of equipment performance evaluations on veterinary radiation machines.

Section 289.226(b)(14) and (15) add clarifying language to differentiate between the definition of a "physician" and a "certified physician" for purposes of the rule.

Section 289.226(b)(16) adds language to clarify that an entity under the jurisdiction of the federal government is not held to the requirements of this section.

In reference to §289.226(d)(5), the term "transmission microscopes" is added to include that they are exempt from the requirements of this section.

Concerning §289.226(e)(5), language is added to clarify that a separate application is required for lasers, laser services, laser hair removal facilities, laser hair removal training programs, and laser hair removal individuals.

In reference to §289.226(f)(1)(B), language is added to permit a person to energize an accelerator for purposes of installation and acceptance testing before receiving a certificate of registration.

Because brachytherapy devices are a new radiation therapy technology that is now regulated, §289.226(f)(6) adds requirements for each person having the device to apply for and receive a certificate of registration from the department before using the device on humans.

Wording in §289.226(h)(2)(H)(i) adds requirements for persons performing healing arts screening to establish a method for patients to ensure proper follow-up care if the screening reveals a condition requiring treatment to select a physician if the patient does not already have one to ensure proper follow-up care if the screening reveals a condition requiring treatment.

In §289.226(j)(5)(A)(iii)(I) - (III), a combination of training and experience is added for those with less formal training, but have additional years of supervised experience, to meet registration compliance requirements for the assembly, installation, and repair of radiation machines.

Section 289.226(m)(3) adds language to clarify that registration of the radiation machines is required prior to use.

Wording is added in §289.226(m)(6) to clarify that a person providing radiation machine services shall ensure that the person transferring, or having a radiation machine installed, shall have evidence of a completed application for registration or be in possession of a current certificate of registration.

Section 289.226(m)(7)(A)(iii) adds language to require that the person notify the department within 30 days if a radiation machine is installed at another use location so the department may document the site of the radiation machine and update the certificate of registration accordingly.

Concerning §289.226(m)(12)(B)(i) - (iii), language is added to require that the provider of radiation machines maintain a log of each machine provided to include the date, and name and registration number of the customer.

For health and safety purposes, §289.226(m)(13)(C) adds a requirement that explicitly prohibits demonstration of radiation machines on humans unless performed by or under the direction of a practitioner of the healing arts.

Section 289.226(n)(1)(A) adds language to require that the radiation safety officer review the operating and safety procedures at intervals not to exceed 12 months to ensure the procedures are current and compliant with rule.

For operator and patient safety, new language is added in §289.226(o)(5) to clarify that an equipment performance evaluation shall be performed on all radiation machines within 30 days of installation, re-installation, or after the repair of a component that might affect the radiation output.

Section 289.226(o)(7)(A) - (B) adds language to clarify the duties of the physicist when supervising a non-physicist in connection with the collection of entrance exposure data.

Section 289.226(q)(1)(A) adds language to permit the registrant's radiation safety officer, owner, or an individual authorized to act on behalf of the registrant, to sign a request for termination of the certificate of registration.

Language is added in §289.226(t)(7) to extend from 1 year to 2 years from the date granted, the reciprocal recognition of a registration from another jurisdiction.

Section 289.226(u) adds language to require that any research using radiation machines on humans is to be approved by an Investigational Review Board to comply with Title 45, Code of Federal Regulations (CFR), Part 46 and Title 21, CFR, Part 56.

The retention period for records of training and experience for the figure referenced in §289.226(v)(1) item (A) is extended to, "until termination of registration or 5 years after the individual terminates employment with the facility," so that pertinent records will be available at the time of inspection by the department.

FISCAL NOTE

Susan E. Tennyson, Section Director, Environmental and Consumer Safety Section, has determined that for each year of the first five years that the sections are in effect, there will be no fiscal implications to state or local government as a result of enforcing and administering the sections as proposed.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Tennyson also has determined that there will be no adverse economic impact on small businesses or micro-businesses required to comply with the sections as proposed. This is determined by interpretation of the rules that small businesses and micro-businesses will not be required to alter their business practices in order to comply with the sections.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no anticipated costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

In addition, Ms. Tennyson also has determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as the result of enforcing or administering these sections is to ensure continued, enhanced protection of the public, patients, workers, and the environment from unnecessary exposure to radiation by ensuring that the rule is clear and specific.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule, the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure, and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state.

TAKING IMPACT ASSESSMENT

The department has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Barbara J. Taylor, Radiation Group, Policy/Standards Quality Assurance Unit, Division of Regulatory Services, Environmental and Consumer Safety Section, Department of State Health Services, Mail Code 1987, P.O. Box 149347, Austin, TX 78714-9347, (512) 834-6770, extension 2010, or by email to BarbaraJ.Taylor@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

PUBLIC HEARING

A public hearing to receive comments on the proposal will be scheduled after publication in the *Texas Register* and will be held at the Department of State Health Services, Exchange Building, 8407 Wall Street, Austin, Texas 78754. The meeting date will be posted on the Radiation Control website (www.dshs.state.tx.us/radiation). Please contact Barbara J. Taylor at (512) 834-6770, extension 2010, or BarbaraJ.Taylor@dshs.state.tx.us if you have questions.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The repeal and new rule are authorized by Health and Safety Code, §401.051, which provides the Executive Commissioner of the Health and Human Services Commission with authority to adopt rules and guidelines relating to the control of radiation; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001. The review of the rule implements Government Code, §2001.039.

The repeal and new rule affect Health and Safety Code, Chapters 401 and 1001; and Government Code, Chapter 531.

Section for Repeal.

§289.226. Registration of Radiation Machine Use and Services.

LEGEND: (Proposed New Rule)
Regular Print=Proposed New Language

§289.226. Registration of Radiation Machine Use and Services.

(a) Purpose.

(1) This section provides for the registration of persons using radiation machines and persons who are in the business of providing radiation machine services.

(2) A person who receives, possesses, uses, owns, or acquires radiation machines prior to receiving a certificate of registration is subject to the requirements of this chapter.

(b) Scope.

(1) In addition to the requirements of this section, all registrants are subject to the requirements of §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections), §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), and §289.231 of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation.)

(2) Registrants using radiation machines in the healing arts are also subject to the requirements of §289.227 of this title (relating to Use of Radiation Machines in the Healing Arts). Morgues, educational facilities, and forensic medicine or investigations utilizing radiation machines for non-human use are subject to the specific requirements of §289.227 of this title.

(3) Registrants using analytical and other industrial radiation machines, such as x-ray equipment used for cathodoluminescence, ion implantation, gauging, or electron beam welding, are subject to the requirements of §289.228 of this title (relating to Radiation Safety Requirements for Industrial Radiation Machines.)

(4) Registrants using accelerators, therapeutic radiation machines, simulators, and electronic brachytherapy devices are also subject to the requirements of §289.229 of this title (relating to Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, Simulators, and Electronic Brachytherapy Devices.)

(5) Registrants using mammography radiation machines are also subject to the requirements of §289.230 of this title (relating to Certification of Mammography Systems and Mammography Machines Used for Interventional Breast Radiography) and §289.234 of this title (relating to Mammography Accreditation.)

(6) Registrants using radiation machines in industrial radiographic operations are also subject to the requirements of §289.255 of this title (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography.)

(7) Registrants using dental radiation machines are subject to the requirements of §289.232 of this title (relating to Radiation Control Regulations for Dental Radiation Machines.)

(8) Registrants using radiation machines in veterinary medicine are subject to the requirements of §289.233 of this title (relating to Radiation Control Regulations for Radiation Machines used in Veterinary Medicine.)

(9) Registrants using laser radiation machines or performing laser services are subject to the requirements of §289.301 of this title (relating to Registration and Radiation Safety Requirements for Lasers and Intense-Pulsed Light Devices) or the requirements of §289.302 of this title (relating to Registration and Radiation Safety Requirements for Use of Laser Hair Removal Devices.)

(10) To determine compliance with the requirements in this chapter for radiation machines used on humans, all radiation exposure rate (air kerma rate) or dose measurements for fluoroscopy or computed tomography radiation machines shall be performed by a licensed physicist with a specialty in diagnostic medical physics.

(11) For purposes of this section, radiation services include but are not limited to:

(A) radiation machines that are not for human use, performance of exposure rate (air kerma rate) or dose measurements;

(B) radiation machines for human use, collecting entrance exposure (air kerma) data for general radiographic and special purpose radiation machines, as defined in §289.227(e) of this title, by or under the supervision of a licensed medical physicist;

(C) radiation machines for human use, performance of services specified in paragraph (10) of this subsection or services requiring a licensed medical physicist as specified in §289.227(e) and §289.229 of this title;

(D) presentation of agency-accepted training courses that are specifically required by this chapter;

(E) demonstration and sale of radiation machines that require the individual to operate or cause a radiation machine to be operated in order to demonstrate or sell;

(F) assembly, installation or repair to ensure a radiation machine is operating according to manufacturer's specifications;

(G) completion of equipment performance evaluations (EPE) on dental radiation machines and on machines used in veterinary medicine; and

(H) providing radiation machines to a facility for limited time periods.

(12) For purposes of this section, a person providing the services described in paragraph (11)(H) of this subsection is a provider of equipment.

(13) For purposes of this section, a practitioner of the healing arts is a person licensed to practice healing arts by either the Texas Medical Board as a physician, the Texas Board of Chiropractic Examiners, or the Texas State Board of Podiatric Medical Examiners.

(14) For purposes of this section, a physician is an individual licensed by the Texas Medical Board.

(15) For purposes of this section, a certified physician is a physician licensed by the Texas Medical Board and certified in radiation oncology or therapeutic radiology.

(16) This section does not apply to an entity under the jurisdiction of the federal government.

(c) Prohibitions.

(1) No person shall expose an individual to radiation for training, demonstration, or other non-healing arts purposes.

(2) No person shall use radiation machines or perform radiation machine services except as authorized in a certificate of registration issued by the agency in accordance with the requirements of this section.

(d) Exemptions.

(1) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this section, provided that the dose equivalent rate averaged over an area of 10 square centimeters (cm^2) does not exceed 0.5 millirem per hour (mrem/hr) (0.005 mSv per hour (mSv/hr)) at 5 centimeters (cm) from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

(2) Radiation machines in transit or in storage incident to transit are exempt from the requirements of this section. This exemption does not apply to the providers of radiation machines for mobile services.

(3) Facilities that have placed all radiation machines in storage, including on-site storage secured from unauthorized use or removal, and have notified the agency in writing, are exempt from the requirements of this section. This exemption is void if any radiation machine is energized resulting in the production of radiation. Prior to resuming use of the machine(s) for human use, the machine shall meet all requirements of this section.

(4) Inoperable radiation machines are exempt from the requirements of this section. For the purposes of this section, an inoperable radiation machine means a radiation

machine that cannot be energized when connected to a power supply without repair or modification.

(5) Domestic television receivers, video display terminals, transmission microscopes, and electron microscopes, including the servicing of such devices, are exempt from the requirements of this section.

(6) A person that takes possession of a radiation machine as the result of foreclosure, bankruptcy, or other default of payment may possess the machine without registering it. If the machine is energized, it shall be under the supervision of a person registered in accordance with this section and shall be energized only to demonstrate that the machine is operable for sale, lease, or transfer purposes.

(7) Facilities, including academic institutions and research or development facilities, registered for the use of radiation machines are exempt from the registration requirements of subsection (j) of this section, regarding radiation services, to the extent that their personnel perform radiation services only for the registrant by whom they are employed.

(e) General requirements for application for registration.

(1) Application for registration shall be completed on forms prescribed by the agency and shall contain all the information required by the form and accompanying instructions. For initial registrations with multiple use locations, a separate application RC Form 226-2 shall be completed for each use location under the registration.

(2) A radiation safety officer (RSO) shall be designated on each application form. The qualifications of that individual shall be submitted to the agency with the application. The RSO shall meet the applicable qualifications specified in paragraph (3) of this subsection and carry out the responsibilities of subsection (n) of this section.

(3) Qualifications for RSOs for registrants (except for industrial radiography.)

(A) All RSOs and laser safety officers shall meet the following general qualifications in addition to qualifications in specific categories:

(i) knowledge of potential radiation hazards and emergency precautions; and

(ii) completed educational courses related to ionizing radiation safety or a radiation safety officer course; or

(iii) experience in the use and familiarity of the type of equipment used.

(B) Specific qualifications for RSOs by facility are as follows.

(i) Healing arts facilities shall have:

(I) a practitioner RSO with documentation of licensing
board number; or

(II) a non-practitioner RSO with at least one of the
following:

(-a-) evidence of a valid general certificate issued
under the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter
601, and at least 2 years of supervised experience and/or supervised use of radiation machines;

(-b-) evidence of a valid limited certificate issued
under the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter
601, and at least 4 years of supervised experience and/or supervised use of radiation machines;

(-c-) evidence of registry by the American Registry
of Radiologic Technologists (ARRT) or the American Registry of Clinical Radiologic
Technologists (ARCRT) and at least 2 years of supervised experience and/or supervised use of
radiation machines;

(-d-) evidence of associate degree in radiologic
technology, health physics, or nuclear technology, and at least 2 years of supervised experience
and/or supervised use of radiation machines;

(-e-) evidence of registration with the Texas Board
of Nursing as a Registered Nurse or a Registered Nurse with an extended scope of practice
(Nurse Practitioner) performing radiologic procedures, and at least 2 years of supervised
experience and/or supervised use of radiation machines in the respective specialty;

(-f-) evidence of registration with the Texas
Physician Assistant Board, and at least 2 years of supervised use of radiation machines in the
respective specialty;

(-g-) for radiation therapy facilities, evidence of
registry by the ARRT or ARCRT and at least 4 years of supervised experience and/or supervised
use of radiation therapy machines;

(-h-) evidence of bachelor's (or higher) degree in
radiologic technology, health physics, or nuclear technology and at least 2 years of supervised
experience and/or supervised use of radiation machines; or

(-i-) evidence of a current Texas license under the
Medical Physics Practice Act, Texas Occupations Code, Chapter 602, in one or more of the
following appropriate specialties:

(-1-) medical health physics, diagnostic medical physics, or nuclear medical physics for diagnostic x-ray facilities; or

(-2-) medical health physics or therapeutic medical physics for radiation therapy facilities.

(ii) Academic institutions and/or research and development facilities shall have RSOs who are faculty or staff members in radiation protection, radiation engineering, or related disciplines. This individual may also serve as the RSO over the healing arts section of the facility.

(iii) Industrial radiography operations shall have a RSO who meets the requirements of §289.255(e)(4)(B) of this title.

(C) The RSO identified on a certificate of registration issued before September 1, 1993, need not comply with the training requirements in this subsection.

(D) The RSO for an application for registration of an electronic brachytherapy device shall meet the qualifications of this subsection and shall carry out the responsibilities of subsection (n) of this section.

(4) Any time after the filing of the original application, the agency may require additional information to determine if the certificate of registration should be issued or denied.

(5) An application for a certificate of registration may include a request for a certificate of registration authorizing one or more activities or use locations. Applications for certification of mammography systems, lasers, laser services, laser hair removal facilities, laser hair removal training programs, and laser hair removal individuals shall be made separately.

(6) Applications and documents submitted to the agency may be made available for public inspection except that the agency may withhold any document or part thereof from public inspection in accordance with §289.231(aa) of this title.

(7) Each application for a certificate of registration shall be accompanied by the fee prescribed in §289.204 of this title. An application for a certificate of registration for an electronic brachytherapy device shall be accompanied by the fee prescribed in §289.204(j)(3) of this title for other therapeutic radiation machines.

(8) Each application shall be accompanied by a completed RC Form 226-1 (Business Information Form) that shall contain the legal name of the entity or business. Unless exempt in accordance with the Business and Commerce Code, Chapter 71, the applicant shall:

(A) be authorized to conduct business in the State of Texas as listed on the Texas Secretary of State (SOS) web site; and

(B) file an assumed name certificate with the Texas SOS if using an assumed name in their application, and/or the office of the county clerk in the county where the business is located.

(f) Application for registration for human use of radiation machines.

(1) In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following.

(A) Each person having a radiation machine used in the healing arts shall apply for registration with the agency within 30 days after beginning use of the radiation machine, except for mobile services that shall be registered in accordance with subsection (g) of this section, and healing arts screening that shall be approved in accordance with subsection (h) of this section.

(B) Each person having an accelerator or therapeutic radiation machine capable of operating at or above 1 million electron volts (MeV) shall apply for and receive a certificate of registration from the agency before using the accelerator for human use. A person may energize the accelerator for purposes of installation and acceptance testing before receiving a certificate of registration from the agency.

(C) Each person having a simulator and/or therapeutic radiation machine capable of operating below 1 MeV for human use shall apply for registration with the agency within 30 days of energizing the equipment.

(2) The applicant shall ensure that radiation machines are operated by individuals qualified by reason of training and experience to use the radiation machine for the purpose requested in accordance with this section in such a manner as to minimize danger to occupational and public health and safety.

(3) An application for healing arts shall be signed by a licensed practitioner. The signature of the administrator, president, or chief executive officer will be accepted in lieu of a licensed practitioner's signature if the facility has more than one licensed practitioner who may direct the operation of radiation machines. The application shall also be signed by the RSO.

(4) An application for accelerators or therapeutic radiation machines, including electronic brachytherapy devices, for human use shall be signed by a physician licensed by the Texas Medical Board. The signature of the administrator, president, or chief executive officer will be accepted in lieu of a physician's signature if the facility has more than one physician who may direct the operation of radiation machines. The application shall also be signed by the RSO.

(5) Each applicant for accelerators or therapeutic radiation machines, other than electronic brachytherapy devices, shall submit:

(A) operating and safety procedures as described in §289.229(h)(1)(G) of this title; and

(B) a description of the proposed facilities.

(6) Each person having an electronic brachytherapy device shall apply for and receive a certificate of registration from the agency before using the device for human use. An application for an electronic brachytherapy device shall include:

(A) a list identifying the radiation safety officer, all certified physicians (except visiting certified physicians), licensed medical physicists, and qualified operators, with documentation of training and education in accordance with §289.229(h)(1)(D) and (E) of this title;

(B) a current copy of the quality assurance program in accordance with §289.229(h)(1)(F) of this title;

(C) a copy of the most current record of surveys, calculations, and quality assurance checks on each device;

(D) a copy of the device manufacturer's United States Food and Drug Administration certification;

(E) a copy of the operating and safety procedures as described in §289.229(h)(1)(G) of this title; and

(F) a description of the proposed facilities showing how the requirements of §289.229(k) of this title are to be met. The description of the proposed facilities shall also include:

(i) a diagram of the physical facility showing the location of the electronic brachytherapy treatment rooms;

(ii) an indication whether the facility is a new structure or a modification to an existing structure; and

(iii) the type and thickness of the portable shielding if used and a procedure demonstrating the use of the shielding prior to treatment.

(7) A separate registration is required for facilities for which one or more of the following applies:

(A) the facilities are not at the same physical address;

(B) the facilities are not under the same radiation safety program; or

(C) the facilities are not under the same management.

(g) Application for registration of mobile service operations.

(1) In addition to the requirements of subsections (e) and (f) of this section or §289.230 of this title, as applicable, each applicant shall apply for and receive authorization from the agency before beginning mobile service operations.

(2) The following shall be submitted:

(A) an established main location where the machine(s), records, etc. will be maintained for inspection. This shall be a street address, not a post office box number;

(B) a sketch or description of the normal configuration of each radiation machine's use, including the operator's position and any ancillary personnel's location during exposures. If a mobile van is used with a fixed machine inside, furnish the floor plan indicating protective shielding and the operator's position; and

(C) a current copy of the applicant's operating and safety procedures regarding radiological practices for protection of patients, operators, employees, and the general public.

(h) Application for registration of healing arts screening.

(1) In addition to the requirements of subsections (e) and (f) of this section, each applicant shall apply for and receive authorization for healing arts screening before initiating a screening program.

(2) Persons requesting approval from the agency for healing arts screening programs shall submit:

(A) name and address of the applicant;

(B) diseases or conditions for which the x-ray examinations are to be used in diagnoses;

(C) a detailed description of the x-ray examinations proposed in the screening program;

(D) a description of the population to be examined in the screening program, for example, age, sex, physical condition, and other appropriate information;

(E) for mobile screening operations, location(s) where radiation machines are maintained;

(F) operating and safety procedures as follows:

(i) for all radiation machines (except bone densitometers) to include:

(I) an evaluation of the radiation machines to be used in the screening program;

(II) documentation that the evaluation was performed by a licensed medical physicist with a specialty in diagnostic medical physics;

(III) the evaluation shall show that the machines satisfy all requirements of this title;

(ii) for bone densitometers, the manufacturer's evaluation of the radiation machine(s) to be used in the screening program;

(G) training data to include:

(i) the qualifications of each individual who will be operating the radiation machine(s);

(ii) the name and address of the physician licensed in Texas who will interpret the radiographs; and

(H) documentation for verification of the following procedures:

(i) a method of recommending a means of selecting a physician for patients who do not have a physician;

(ii) a description of the procedures to be used in advising the individuals screened and their practitioners of the results of the screening procedure and any further medical needs indicated; and

(iii) a description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations.

(i) Application for registration of radiation machines for non-human use, including use in morgues, forensic medicine or investigations, and educational facilities.

(1) In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following.

(A) Each person having an accelerator for non-human use shall apply for and receive a certificate of registration from the agency before beginning use of the accelerator. A person may energize the accelerator for purposes of installation and testing before receiving a certificate of registration from the agency.

(B) Each person having an accelerator for non-human use shall submit:

(i) operating and safety procedures as described in §289.229(f)(3)(B) of this title; and

(ii) a description of the applicant's proposed facilities in accordance with §289.229(f)(2) and (f)(3)(A), (D) and (E) of this title.

(2) Each person having a radiation machine for non-human use, other than those specified in paragraph (1)(A) of this subsection and those used for industrial radiographic operations, shall apply for registration with the agency within 30 days after beginning use of the machine.

(3) Each applicant for use of radiation machines in industrial radiographic operations shall submit the information required in §289.255(t)(1) of this title before beginning use of the machine(s).

(4) An application for the uses specified in this subsection shall be signed by the applicant, registrant, or a person duly authorized to act for and on the applicant's or registrant's behalf. The application shall also be signed by the RSO.

(j) Application for registration of radiation machine services.

(1) In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following.

(A) Each person who intends to provide radiation services described in subsection (b)(11) of this section shall apply for and receive a certificate of registration from the agency before providing the service.

(B) An application for radiation services shall be signed by the applicant or registrant or a person duly authorized to act for and on the applicant's or registrant's behalf. The application shall also be signed by the RSO.

(2) The applicant shall document the qualifications of the specific training and experience that qualifies each individual to perform the service as follows:

(A) for individuals performing assembly, installation, or repair of radiation machines in subsection (b)(11)(F) of this section, document the qualifications listed in paragraph (5) of this subsection;

(B) for individuals performing the services specified in subsections (b)(10) and (11)(C) of this section, obtain a copy of the individual's license from the Texas Board of Licensure for Professional Medical Physicists; and

(C) for all other services, document the qualifications listed in paragraph (5) of this subsection.

(3) No person shall provide services specified in subsections (b)(10) and (11) of this section that are not specifically authorized by the agency.

(4) No person shall provide radiation machine services for a person who cannot produce evidence of a completed application for registration or a valid certificate of registration issued by the agency except for:

(A) services specified in subsection (b)(11)(B), (C) and (E) of this section;
or

(B) the initial installation of the first machine(s) for a new certificate of registration.

(5) Minimum education and training for persons performing radiation machine assembly, installation or repair.

(A) All persons performing radiation machine assembly, installation or repair shall meet one of the following requirements:

(i) 1 year of formal training (may be satisfied by factory school, military technical training school, or other courses in radiation machine assembly, installation or repair techniques) or an associate's degree in biomedical equipment repair;

(ii) a bachelor's degree in electrical engineering with specialized training in radiation producing devices; or

(iii) a combination of training and experience totaling 1 year to include:

(I) experience or education providing familiarity with the type(s) of equipment to be serviced, to include radiation safety;

(II) knowledge of protective measures to reduce potentially hazardous conditions; and

(III) 6 months of supervised assembly and repair of the type(s) of equipment to be serviced.

(B) A registrant holding a valid certificate of registration who has hired individuals to perform services before September 1, 1993, need not comply with the education and training requirements in this paragraph. Individuals hired on or after September 1, 1993, shall comply with the education and training requirements in this paragraph.

(6) Each applicant for providers of equipment shall also submit:

(A) an established main location where the radiation machines, records, etc., will be maintained for inspection. This shall be a street address, not a post office box number; and

(B) a current copy of the applicant's operating and safety procedures which is required when personnel are provided in addition to equipment.

(7) Each applicant for agency-accepted training courses specifically required by §289.253 of this title (relating to Radiation Safety Requirements for Well Logging Service Operation and Tracer Studies), and §289.255 of this title shall also submit:

(A) a course syllabus;

(B) the number of instructional hours for each subject;

(C) a list of training resources, for example, reference books, texts, workbooks, physical facilities, etc.;

(D) all test questions and corresponding answers; and

(E) the radiation safety training, education, and experience of each instructor.

(8) A record documenting the qualifications of each individual that performs the service shall be made and maintained for inspection by the agency in accordance with subsection (v) of this section.

(k) Issuance of certificates of registration.

(1) A certificate of registration application will be approved if the agency determines that an application meets the requirements of the Texas Radiation Control Act (Act) and the requirements of this chapter. The certificate of registration authorizes the proposed activity in the form and contains the conditions and limitations as the agency deems appropriate or necessary.

(2) The agency may incorporate in the certificate of registration at the time of issuance, or thereafter by amendment, additional requirements and conditions concerning the registrant's possession, use, and transfer of radiation machines subject to this chapter as it deems appropriate or necessary in order to:

(A) minimize danger to occupational and public health and safety;

(B) require additional reports and the keeping of additional records as may be appropriate or necessary; and

(C) prevent loss or theft of radiation machines subject to this section.

(3) The agency may request, and the registrant shall provide, additional information after the certificate of registration has been issued to enable the agency to determine whether the certificate of registration should be modified in accordance with subsection (s) of this section.

(l) Terms and conditions of certificates of registration.

(1) Each certificate of registration issued in accordance with this section shall be subject to the applicable provisions of the Act, now or hereafter in effect, and to the applicable rules and orders of the agency.

(2) No certificate of registration issued or granted under this section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, to any person unless the agency authorizes the transfer in writing.

(3) Each person registered by the agency for radiation machine use in accordance with this section shall confine use and possession of the radiation machine registered to the locations and purposes authorized in the certificate of registration.

(4) In making a determination whether to grant, deny, amend, renew, revoke, suspend, or restrict a certificate of registration, the agency may consider the technical competence and compliance history of an applicant or holder of a certificate of registration. After an opportunity for a hearing, the agency shall deny an application for a certificate of registration, an amendment to a certificate of registration, or renewal of a certificate of registration if the applicant's compliance history reveals that at least three agency actions have been issued against the applicant, within the previous 6 years, that assess administrative or civil penalties against the applicant, or that revoke or suspend the certificate of registration.

(m) Responsibilities of registrant.

(1) The registrant is responsible for complying with this chapter and the conditions of the certificate of registration.

(2) The registrant shall designate an individual qualified in accordance with subsection (e)(3) of this section as the radiation safety officer and shall ensure the individual continually performs the responsibilities of the radiation safety officer as identified in subsection (n) of this section.

(3) Persons using radiation machines in accordance with subsections (f)(1)(B) (concerning radiation accelerator or therapeutic radiation machines for human use), (g) (concerning application for mobile service operations), (i)(1)(A) (concerning persons having an accelerator for non-human use), and (i)(3) of this section (concerning radiation machines in

industrial radiographic operations) of this section shall have a valid certificate of registration issued by the agency prior to use.

(4) Other than the initial installation of the first machines(s) for a new certificate of registration, no person shall use radiation machines unless they have applied for registration within 30 days of beginning use of the machines in accordance with subsection (f)(1)(A) of this section.

(5) No registrant shall engage any person for services described in subsection (b)(11) of this section until the person provides to the registrant evidence of registration with the agency.

(6) No person shall provide radiation machine services for a person who cannot produce evidence of a completed application for registration or a valid certificate of registration issued by the agency except for:

(A) the initial installation of the first machines(s) for a new certificate of registration; and

(B) the registrant authorized for demonstration and sale may demonstrate a radiation machine in accordance with paragraph (13) of this subsection.

(7) The registrant shall notify the agency of any changes that would render the information contained in the application for registration and/or the certificate of registration inaccurate. The notification shall be in writing and signed by an authorized representative.

(A) Notification is required within 30 days of the following changes:

(i) name or mailing address;

(ii) street address where machine will be used;

(iii) additional use location;

(iv) RSO; or

(v) name and registration number of the contracted "provider of equipment," registered in accordance with this section.

(B) The registrant shall notify the agency within 30 days of changes in the radiation machines that include:

(i) any change in the category(ies) of machine type or type of use as specified in §289.231(11) of this title and as authorized in the certificate of registration; or

(ii) any increase in the number of machines authorized by the certificate of registration in any machine type or type of use category.

(8) The registrant, or the parent company, shall notify the agency in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy. This notification shall include:

(A) the bankruptcy court in which the petition for bankruptcy was filed;
and

(B) the case name and number, and date of filing the petition.

(9) The registrant shall inventory all radiation machines in the registrant's possession at an interval not to exceed 1 year.

(A) The inventory shall include:

(i) manufacturer's name;

(ii) model and serial number of the control panel; and

(iii) location of radiation machine(s) (for example, room number.)

(B) Records of the inventory shall be made and maintained for inspection by the agency in accordance with subsection (v) of this section.

(10) The registrant shall maintain records of receipt, transfer, and disposal of radiation machines.

(A) The records shall include:

(i) manufacturer's name;

(ii) model and serial number from the control panel;

(iii) date of the receipt, transfer, and disposal;

(iv) name and address of person machine(s) received from, transferred to, or disposed of; and

(v) name of the individual recording the information.

(B) Records of the receipt, transfer or disposal of the machine(s) shall be made and maintained for inspection by the agency in accordance with subsection (v) of this section.

(11) The persons using loaner radiation machines shall comply with the following.

(A) For persons having a valid certificate of registration, loaner radiation machines may be used for up to 30 days. Within the following 30 days, the registrant shall:

(i) notify the agency of a change in the category(ies) of machine type or type of use as specified in §289.231(II) of this title and as authorized in the certificate of registration; or

(ii) notify the agency of any increase in the number of machines authorized by the certificate of registration in any machine type or type of use category; and

(iii) perform an equipment performance evaluation on the radiation machine(s) in accordance with §289.227(o) of this title.

(B) For persons who do not hold a valid certificate of registration, loaner radiation machines may be used for human use up to 30 days, by or under the direction of a practitioner, before applying for a certificate of registration in accordance with subsection (e) of this section. This does not include:

(i) accelerators for human use as described in subsection (f)(1)(B) of this section;

(ii) mobile services as described in subsection (g) of this section;

(iii) healing arts screening as described in subsection (h) of this section;

(iv) accelerators for non-human use as described in subsection (i)(1)(A) of this section; and

(v) industrial radiography as described in subsection (i)(3) of this section.

(12) Persons authorized to provide radiation machines shall comply with the following.

(A) Providers of equipment shall:

(i) ensure that all radiation machines used on humans for healing arts purposes meet the requirements of §289.227(o) of this title; and

(ii) provide radiation machines only to facilities holding a valid certificate of registration.

(B) Providers of equipment shall keep a log of radiation machines provided in Texas. The record shall list the following current information:

- (i) date machine is provided;
- (ii) name of customer; and
- (iii) customer's certificate of registration number.

(C) Records of machines provided shall be made and maintained for inspection by the agency in accordance with subsection (v) of this section.

(13) Persons authorized to perform demonstration and sale of radiation machines in Texas shall comply with the following.

(A) A daily log shall be maintained and shall include:

- (i) date of all demonstrations and sales of radiation machines performed in Texas;
- (ii) name and address of customer; and
- (iii) customer's certificate of registration number, unless the service provided is an initial installation as described in paragraph (6) of this subsection.

(B) Records of all demonstrations and sales shall be made and maintained for inspection by the agency in accordance with subsection (v) of this section.

(C) Demonstration of radiation machines on humans shall be performed by or under the direction of a practitioner in accordance with paragraph (11) of this subsection.

(D) Demonstration of radiation machines performed by the service provider shall be on phantoms only.

(E) The registrant authorized for demonstration and sale of radiation machines is responsible for performing all tests in accordance with §289.227 of this title for radiation machines used on humans for demonstration purposes.

(n) Responsibilities of RSOs.

(1) Duties of the RSO include, but are not limited to:

(A) establishing and overseeing operating and safety procedures that maintain radiation exposures as low as reasonably achievable (ALARA), and to review them at intervals not to exceed 12 months to ensure that the procedures are current and conform with this chapter;

(B) ensuring that individual monitoring devices are properly used by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by §289.203 of this title;

(C) investigating and reporting to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this chapter;

(D) assuming control and having the authority to institute corrective actions including shut-down of operations when necessary in emergency situations or unsafe conditions; and

(E) maintaining records as required by this chapter.

(2) The RSO shall ensure that personnel are adequately trained and complying with this chapter, the conditions of the certificate of registration, and the operating and safety procedures of the registrant.

(o) Responsibilities of assemblers and/or installers.

(1) No person shall provide radiation machine services for a person who cannot produce evidence of a completed application for registration or a valid certificate of registration issued by the agency except for the initial installation of the first machine(s) for a new certificate of registration.

(2) Persons who assemble or install radiation machines shall notify the agency of the following information within 30 days of installation:

(A) the name, address, and certificate of registration number, except in the case of initial machine installation, of persons who have received the machines;

(B) the type of radiation machine, the manufacturer's name, model number, and control panel serial number of each radiation machine; and

(C) the date of transfer or disposal of each radiation machine.

(3) Persons who assemble, install, or repair radiation machines, or components of the machines, shall ensure the radiation machines meet the applicable requirement of this chapter when the machines are placed in operation.

(4) Persons assembling, installing, and repairing radiation machines shall keep a daily log to include:

(A) date;

(B) name of customer;

(C) customer's certificate of registration number unless the installation is an initial installation described in paragraph (1) of this subsection; and

(D) records of assembling, installing and repairing of the machines shall be made and maintained for inspection by the agency in accordance with subsection (v) of this section.

(5) Equipment performance evaluations shall be performed as follows:

(A) on all medical, chiropractic or podiatric radiation machines within 30 days after the initial installation, re-installation, and after repair of a machine component that would affect the radiation output that includes but is not limited to the timer, tube, power supply, and thereafter, in accordance with §289.227(o)(1) of this title; and

(B) on all dental radiation machines and radiation machines used in veterinary medicine within 30 days after the initial installation, re-installation, and after repair of a machine component that would affect the radiation output that includes but is not limited to the timer, tube, and power supply, and thereafter, in accordance with §289.232(i)(7) and §289.233(i)(5)(N) of this title.

(6) Radiation exposure rate (air kerma rate) or dose measurements for fluoroscopy and computed tomography (CT) radiation machines, as required by §289.227 of this title, shall be performed by a licensed medical physicist with a specialty in diagnostic medical physics.

(7) Radiation entrance exposure (air kerma) data required during EPEs on general radiographic and special purpose radiation machines, as defined in §289.227(e) of this title, shall be performed by or under the supervision of a licensed medical physicist with a specialty in diagnostic medical physics. The physicist shall:

(A) establish written procedures for non-physicists that document entrance exposure (air kerma) data;

(B) calculate the entrance exposure (air kerma);

(C) verify the entrance exposure (air kerma) meets compliance with §289.227(j) of this title; and

(D) sign the EPE reports.

(p) Expiration of certificates of registration.

(1) Except as provided by subsection (r) of this section, each certificate of registration expires at the end of the day, in the month and year stated in the certificate of registration.

(2) If a registrant does not submit an application for renewal of the certificate of registration in accordance with subsection (r) of this section, as applicable, on or before the expiration date specified in the certificate of registration, the registrant shall:

(A) terminate use of all radiation machines and/or terminate radiation machine servicing or radiation services; and

(B) pay any outstanding fees in accordance with §289.204 of this title.

(3) Expiration of the certificate of registration does not relieve the registrant of the requirements of this chapter.

(q) Termination of certificates of registration.

(1) When a registrant decides to terminate all activities involving radiation machines or services authorized under the certificate of registration, the registrant shall immediately:

(A) request termination of the certificate of registration in writing signed by the RSO, owner, or an individual authorized to act on behalf of the registrant; and

(B) submit to the agency a record of the disposition of the radiation machines, if applicable; and if transferred, to whom they are transferred.

(2) The registrant shall pay any outstanding fees in accordance with '289.204 of this title.

(r) Renewal of certificates of registration.

(1) An application for renewal of a certificate of registration shall be filed in accordance with subsection (e) of this section and applicable paragraphs of subsections (f) - (j) of this section.

(2) If a registrant files an application for a renewal in proper form before the existing certificate of registration expires, such existing certificate of registration shall not expire until the application status has been determined by the agency.

(s) Modification, suspension, and revocation of certificates of registration.

(1) The terms and conditions of all certificates of registration shall be subject to revision or modification. A certificate of registration may be suspended or revoked by reason of amendments to the Act, by reason of rules in this chapter or orders issued by the agency.

(2) Any certificate of registration may be revoked, suspended, or modified, in whole or in part, for:

(A) any material false statement in the application or any statement of fact required under provisions of the Act;

(B) conditions revealed by such application or statement of fact or any report, record, or inspection, or other means that would warrant the agency to refuse to grant a certificate of registration on an original application;

(C) violation of, or failure to observe any of the terms and conditions of the Act, this chapter, the certificate of registration, or order of the agency; or

(D) existing conditions that constitute a substantial threat to the public health or safety or the environment.

(3) Each certificate of registration revoked by the agency ends at the end of the day on the date of the agency's final determination to revoke the certificate of registration, or on the revocation date stated in the determination, or as otherwise provided by the agency order.

(4) Except in cases in which the occupational and public health or safety requires otherwise, no certificate of registration shall be suspended or revoked unless, prior to the institution of proceedings therefore, facts or conduct that may warrant such action shall have been called to the attention of the registrant in writing and the registrant shall have been afforded an opportunity to demonstrate compliance with all lawful requirements.

(t) Reciprocal recognition of out-of-state certificates of registration.

(1) Whenever any radiation machine is to be brought into the state for any temporary use, the person proposing to bring the machine into the state shall apply for and receive a notice from the agency granting reciprocal recognition prior to beginning operations. The request for reciprocity shall include a:

(A) completed RC Form 226-1 (Business Information Form);

(B) completed RC Form 226-3 (Application for Registration of Industrial Radiation Machines);

(C) completed BRC Form 252-3 (Notice of Intent to Work in Texas Under Reciprocity);

(D) completed qualification forms (BRC Forms 255-E, 255-T and/or 255-OS) for each radiographer who will be working in Texas if the reciprocity request is for industrial radiography;

(E) name and Texas licensing board number of the practitioner if the radiation machines are used on humans;

(F) copy of the applicant's current certificate of registration or equivalent document;

(G) copy of the applicant's current operating and safety procedures pertinent to the proposed use;

(H) fee as specified in §289.204(d) of this title; and

(I) qualifications of personnel who will be operating the machines for human use.

(2) Upon a determination that the request for reciprocity meets the requirements of the agency, the agency may issue a notice granting reciprocal recognition authorizing the proposed use.

(3) Once reciprocity is granted, the out-of-state registrant shall file a BRC Form 252-3 with the agency prior to each entry into the state. This form shall be filed at least 3 working days before the radiation machine is to be used in the state. If, for a specific case, the 3-day period would impose an undue hardship, the out-of-state registrant may, at the determination of the agency, obtain permission to proceed sooner.

(4) When radiation machines are used as authorized under reciprocity, the out-of-state registrant shall have the following in its possession at all times for inspection by the agency:

(A) completed BRC Form 252-3;

(B) copy of the notice from the agency granting reciprocity;

(C) copy of the out-of-state registrants operating and safety procedures;
and

(D) copy of the applicable rules as specified in the notice granting reciprocity.

(5) If the state from which the radiation machine is proposed to be brought does not issue certificates of registration or equivalent documents, a certificate of registration shall be obtained from the agency in accordance with the requirements of this section.

(6) The agency may withdraw, limit, or qualify its acceptance of any certificate of registration or equivalent document issued by another agency upon determining that the action is necessary in order to prevent undue hazard to occupational and public health and safety or property.

(7) Reciprocal recognition will expire 2 years from the date it is granted. A new request for reciprocity shall be submitted to the agency every 2 years. Reciprocity requests made after the initial request shall include the following:

- (A) completed RC Form 226-1(Business Information Form);
- (B) completed RC Form 226-3 (Application for Registration of Industrial Radiation Machines);
- (C) completed BRC Form 252-3 (Notice of Intent to Work in Texas Under Reciprocity);
- (D) completed qualification forms (BRC Forms 255-E, 255-T and/or 255-OS for each radiographer who will be working in Texas if the reciprocity request is for industrial radiography;
- (E) name and Texas licensing board number of the practitioner if the radiation machines are used on humans;
- (F) copy of the applicant's current certificate of registration or equivalent document;
- (G) copy of the applicant's current operating and safety procedures pertinent to the proposed use;
- (H) fee as specified in §289.204(d) of this title; and
- (I) qualifications of personnel who will be operating the machines.

(8) Radiation services provided by a person from out-of-state will not be granted reciprocity. Whenever radiation services are to be provided by a person from out-of-state, that person shall apply for and receive a certificate of registration from the agency before providing radiation services. The application shall be filed in accordance with subsections (e), (i), and (j) of this section, as applicable.

(u) Medical research and investigational devices.

(1) Any research using radiation machines on humans shall be approved by an Investigational Review Board (IRB) as required by Title 45, Code of Federal Regulations (CFR), Part 46 and Title 21, CFR, Part 56. The IRB shall include at least one physician to direct any use of radiation in accordance with §289.231(b) of this title.

(2) Facilities with radiation machines with investigational device exemptions that are involved in clinical studies shall comply with primary regulations that govern the conduct of clinical studies and that apply to the manufacturers, sponsors, clinical investigators, institutional review boards, and the medical device. These regulations include:

- (A) 21 CFR, Part 812, Investigational Device Exemptions;

(B) 21 CFR, Part 50, Protection of Human Subjects;

(C) 21 CFR, Part 56, Institutional Review Boards;

(D) 21 CFR, Part 54, Financial Disclosure by Clinical Investigators; and

(E) 21 CFR, Part 821, Subpart C, Design Controls of the Quality System Regulation.

(v) Record/document retention requirements for registration of radiation machines.

(1) Each registrant shall maintain the following records/documents at each site, including authorized records sites for mobile services, at the time intervals specified for inspection by the agency.

Figure: 25 TAC §289.226(v)(1)

(2) Records listed in paragraph (1) of this subsection may be maintained in electronic format.

Figure: 25 TAC §289.226(v)(1)

	Name of Records/Documents	Rule Cross Reference	Time Interval for Keeping Records/Documents
(A)	Records of training and experience	§289.226(j)(8)	Until termination of registration or 5 years after the individual terminates employment with the facility
(B)	Inventory of radiation machines	§289.226(m)(9)	3 years
(C)	Receipt, transfer, and disposal of radiation machines	§289.226(m)(10)	Until termination of registration
(D)	Radiation machine log for providers of equipment.	§289.226(m)(12)(B)	10 years
(E)	Demonstration and sale log for radiation machines	§289.226(m)(13)(B)	10 years
(G)	RSO annual review of operating and safety procedures	§289.226(n)(1)(A)	3 years
(H)	Assemble, installation, and repair log for radiation machines	§289.226(o)(4)(D)	10 years

~~§289.226. Registration of Radiation Machine Use and Services~~

~~(a) Purpose. This section provides for the registration of persons using radiation machines and persons who are in the business of providing radiation machine installation or radiation services. No person shall use radiation machines or perform radiation services except as authorized in a certificate of registration issued by the agency in accordance with the requirements of this section. A person who receives, possesses, uses, owns, or acquires radiation machines prior to receiving a certificate of registration is subject to the requirements of this chapter.~~

~~(b) Scope.~~

~~—(1) In addition to the requirements of this section, all registrants are subject to the requirements of §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections), §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), and §289.231 of this title (relating to General Provisions and Standards for Protection Against Machine Produced Radiation).~~

~~—(2) Registrants using radiation machines in the healing arts are also subject to the requirements of §289.227 of this title (relating to Use of Radiation Machines in the Healing Arts). Morgues and educational facilities utilizing radiation machines for non-human use are subject to the specific requirements of §289.227 of this title.~~

~~—(3) Registrants using analytical and other industrial radiation machines, such as x-ray equipment used for cathodoluminescence, ion implantation, gauging, or electron beam welding, are subject to the requirements of §289.228 of this title (relating to Radiation Safety Requirements for Industrial Radiation Machines).~~

~~—(4) Registrants using accelerators, therapeutic radiation machines, and simulators are also subject to the requirements of §289.229 of this title (relating to Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, and Simulators).~~

~~—(5) Registrants using mammography radiation machines are also subject to the requirements of §289.230 of this title (relating to Certification of Mammography Systems and Mammography Machines Used for Interventional Breast Radiography) and §289.234 of this title (relating to Mammography Accreditation).~~

~~—(6) Registrants using radiation machines in industrial radiographic operations are also subject to the requirements of §289.255 of this title (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography).~~

~~—(7) Registrants using dental radiation machines are subject to the requirements of §289.232 of this title (relating to Radiation Control Regulations for Dental Radiation Machines).~~

~~—(8) Registrants using veterinary radiation machines are subject to the requirements of §289.233 of this title (relating to Radiation Control Regulations for Veterinary Radiation Machines).~~

~~—(9) For radiation machines for human use, performance of exposure rate or dose measurements to determine compliance with exposure rate or dose measurement requirements of diagnostic radiation machines in this chapter must be performed by a licensed medical physicist with a specialty in diagnostic radiological physics.~~

~~—(10) For the purposes of this section, radiation services shall include, but may not be limited to the following:~~

~~—(A) for radiation machines that are not for human use, performance of exposure rate or dose measurements;~~

~~—(B) for radiation machines for human use, gathering of radiation machine output measurements under the direction of a licensed medical physicist;~~

~~—(C) for radiation machines for human use, performance of services specified in paragraph (9) of this subsection or services requiring a licensed medical physicist as specified in §289.229 of this title;~~

~~—(D) presentation of agency accepted training courses that are specifically required by this chapter;~~

~~—(E) calibration of survey and radiation measurement instruments;~~

~~—(F) demonstration and sales of radiation machines that require the individual to operate or cause a radiation machine to be operated in order to demonstrate or sell;~~

~~—(G) assembly, installation or repair to ensure a radiation machine is operating according to manufacturer's specifications;~~

~~—(H) completion of equipment performance evaluations on dental radiation machines;~~

~~—(I) provision of radiation machines on a routine basis to a facility for limited time periods. For purposes of this section, a person providing the services described in this subparagraph is a provider of equipment. For healing arts facilities, the use of radiation machines shall be directed by a practitioner associated with the contracting facility.~~

~~—(11) For purposes of this section, a practitioner of the healing arts is a person licensed to practice healing arts by either the Texas Medical Board as a physician, the Texas Board of Chiropractic Examiners, or the Texas State Board of Podiatric Medicine.~~

~~(c) Prohibition. Exposure of an individual for training, demonstration, or other non-healing arts purposes is prohibited.~~

~~(d) Exemptions.~~

~~—(1) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this section, provided that the dose equivalent rate averaged over an area of 10 square centimeters (cm^2) does not exceed 0.5 millirem per hour (mrem/hr) at 5 centimeters (cm) from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.~~

~~—(2) Radiation machines in transit or in storage incident to transit are exempt from the requirements of this section. This exemption does not apply to the providers of radiation machines for mobile services. Facilities that have placed all radiation machines in storage, including on-site storage, and have notified the agency in writing, are exempt from the requirements of this section. This exemption is void if any radiation machine is energized resulting in the production of radiation.~~

~~—(3) Domestic television receivers, video display terminals, and electron microscopes, including the servicing of such devices, are exempt from the requirements of this section.~~

~~—(4) Inoperable radiation machines are exempt from the requirements of this section. For the purposes of this section, an inoperable radiation machine means a radiation machine that cannot be energized when connected to a power supply without repair or modification.~~

~~—(5) Financial institutions that take possession of radiation machines as the result of foreclosure, bankruptcy, or other default of payment are exempt from the requirements in this section to the extent that they demonstrate that the unit is operable for the sole purpose of selling, leasing, or transferring.~~

~~—(6) Facilities, including academic institutions and research or development facilities, registered for the use of radiation machines are exempt from the registration requirements of subsection (j) of this section, regarding radiation services, to the extent that their personnel perform radiation services only for the registrant by whom they are employed.~~

~~(e) General requirements for application for registration.~~

~~—(1) Application for registration shall be completed on forms prescribed by the agency and shall contain all the information required by the form and accompanying instructions.~~

~~—(2) A radiation safety officer (RSO) shall be designated on each application form. The qualifications of that individual shall be submitted to the agency with the application. The RSO shall meet the applicable requirements of subsection (t)(1) of this section and carry out the responsibilities of subsection (t)(2) of this section.~~

~~—(3) The agency may at any time after the filing of the original application, require further statements in order to enable the agency to determine whether the certificate of registration should be issued or denied.~~

~~—(4) An application for a certificate of registration may include a request for a certificate of registration authorizing one or more activities. Applications for certification of mammography systems shall be made separately.~~

~~—(5) Applications and documents submitted to the agency may be made available for public inspection except that the agency may withhold any document or part thereof from public inspection in accordance with §289.231(aa) of this title.~~

~~—(6) Each application for a certificate of registration shall be accompanied by the fee prescribed in §289.204 of this title.~~

~~—(7) Each application shall be accompanied by a completed BRC Form 226-1 (Business Information Form).~~

~~(f) Application for registration for human use of radiation machines. In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following:~~

~~—(1) Each person having a radiation machine used in the healing arts shall apply for registration with the agency within 30 days after beginning use of the radiation machine, except for mobile services that shall be registered in accordance with subsection (g) of this section, and healing arts screening and medical research programs that shall be approved in accordance with subsection (h) of this section.~~

~~—(2) Each person having an accelerator or therapeutic radiation machine at or above 1 million electron volts (MeV) for human use shall apply for and receive a certificate of registration from the agency before energizing the accelerator, including performing acceptance testing.~~

~~—(3) Each person having a simulator and/or therapeutic radiation machine below 1 MeV for human use shall apply for registration with the agency within 30 days of energizing the equipment.~~

~~—(4) The applicant shall be qualified by reason of training and experience to use the radiation machine for the purpose requested in accordance with this section in such a manner as to minimize danger to occupational and public health and safety.~~

~~—(5) The applicant's proposed equipment, facilities, and operating and safety procedures shall be adequate to minimize danger to occupational and public health and safety.~~

~~—(6) An application for healing arts shall be signed by a licensed practitioner. The signature of the administrator, president, or chief executive officer will be accepted in lieu of a licensed practitioner's signature if the facility has more than one licensed practitioner who may direct the operation of radiation machines. The application shall also be signed by the RSO if the RSO is someone other than the licensed practitioner.~~

~~—(7) An application for accelerators or therapeutic radiation machines for human use shall be signed by a practitioner licensed by the Texas Medical Board. The signature of the administrator, president, or chief executive officer will be accepted in lieu of a licensed practitioner's signature if the facility has more than one licensed practitioner who may direct the operation of radiation machines. The application shall also be signed by the RSO if the RSO is someone other than the licensed practitioner. Each applicant shall submit operating and safety procedures as described in §289.229(h)(1)(D) of this title and a description of the proposed facilities in accordance with the following:~~

~~—(A) §289.229(h)(2)(B) and (C) of this title for equipment with energies below 1 MeV; and~~

~~—(B) §289.229(h)(3)(B) of this title for equipment with energies above 1 MeV.~~

~~(g) Application for registration of mobile service operation. In addition to the requirements of subsections (e) and (f) of this section or §289.230 of this title, as applicable, each applicant shall apply for and receive authorization for mobile service operation before beginning mobile service operation. The following shall be submitted:~~

~~—(1) an established main location where the machine(s), records, etc. will be maintained for inspection. This shall be a street address, not a post office box number;~~

~~—(2) a sketch or description of the normal configuration of each radiation machine's use, including the operator's position and any ancillary personnel's location during exposures. If a mobile van is used with a fixed unit inside, furnish the floor plan indicating protective shielding and the operator's location; and~~

~~—(3) a current copy of the applicant's operating and safety procedures regarding radiological practices for protection of patients, operators, employees, and the general public.~~

~~(h) Application for registration of healing arts screening and medical research:~~

~~—(1) In addition to the requirements of subsections (e) and (f) of this section, each applicant shall apply for and receive authorization for healing arts screening before initiating a screening program. The information and evaluation in subsection (t)(4) of this section shall be submitted with the application.~~

~~—(2) In addition to the requirements of subsections (e) and (f) of this section, any research using radiation machines on humans shall be approved by an Institutional Review Board (IRB) as required by Title 45, Code of Federal Regulations (CFR), Part 46 and Title 21, CFR, Part 56. The IRB shall include at least one practitioner of the healing arts to direct any use of radiation in accordance with §289.231(b)(1) of this title.~~

~~(i) Application for registration of radiation machines for non-human use, including use in morgues. In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following:~~

~~—(1) Each person having an accelerator for non-human use shall apply for and receive a certificate of registration from the agency before beginning use of the accelerator.~~
~~—(2) Each person having an accelerator for non-human use shall submit the following:~~
~~—(A) operating and safety procedures as described in §289.229(f)(3)(B) of this title; and~~
~~—(B) a description of the applicant's proposed facilities in accordance with §289.229(f)(2) and (f)(3)(A), (D) and (E) of this title.~~
~~—(3) Each person having a radiation machine for non-human use, other than those specified in paragraph (1) of this subsection and those used for industrial radiographic operations, shall apply for registration with the agency within 30 days after beginning use of the machine.~~
~~—(4) Each applicant for use of radiation machines in industrial radiographic operations shall submit the information required in §289.255(t)(1) of this title before beginning use of the machine(s).~~
~~—(5) An application for the uses specified in this subsection shall be signed by the applicant or registrant or a person duly authorized to act for and on the applicant's or registrant's behalf. The application shall also be signed by the RSO if the RSO is someone other than the applicant or registrant.~~

~~(j) Application for registration of radiation machine services. In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following.~~

~~—(1) Each person who intends to provide radiation services described in subsection (b)(10) of this section shall apply for and receive a certificate of registration from the agency before providing such service.~~
~~—(2) An application for radiation services shall be signed by the applicant or registrant or a person duly authorized to act for and on the applicant's or registrant's behalf. The application shall also be signed by the RSO if the RSO is someone other than the applicant or registrant.~~
~~—(3) The applicant shall submit written documentation to the agency of the specific training and experience that qualifies each individual to discharge the duties of this service. As a minimum, each applicant shall submit the following:~~
~~—(A) for individuals performing assembly, installation, or repair of radiation machines in subsection (b)(10)(G) of this section, the qualifications listed in subsection (t)(3) of this section;~~
~~—(B) for individuals performing the services specified in subsection (b)(9) and (10)(C) of this section, a copy of the individual's license from the Texas Board of Licensure for Professional Medical Physicists;~~
~~—(C) for all other services, the qualifications listed in subsection (t)(1)(A)(i) — (iii) of this section.~~
~~—(4) No person shall perform services specified in subsection (b)(9) and (10) of this section that are not specifically authorized by the agency.~~
~~—(5) No person shall perform radiation machine services, other than initial installation of the first machine(s) on the premises, for an individual who cannot produce evidence of registration with the agency authorizing the possession and use of the machines in question.~~
~~—(6) Each applicant for providers of equipment shall also submit the following:~~
~~—(A) an established main location where the machines, records, etc., will be maintained for inspection. This shall be a street address, not a post office box number;~~
~~—(B) evidence that the healing arts facility responsible for administering or supervising the administering of radiation is registered in accordance with the requirements in this section; and~~

~~—(C) a current copy of the applicant's operating and safety procedures. A current copy of the applicant's operating and safety procedures is required when personnel are provided in addition to equipment.~~

~~—(7) Each applicant for calibration of survey and radiation measurement instruments shall also submit the following:~~

~~—(A) procedures for calibration;~~

~~—(B) qualifications of personnel performing the calibration;~~

~~—(C) a copy of the calibration certificate to be used; and~~

~~—(D) a copy of the expiration sticker to be used.~~

~~—(8) Each applicant for agency accepted training courses specifically required by §289.253 (relating to Radiation Safety Requirements for Well Logging Service Operation and Tracer Studies), and §289.255 of this title shall also submit the following:~~

~~—(A) a course syllabus;~~

~~—(B) the number of instructional hours for each subject;~~

~~—(C) a list of training resources, for example, reference books, texts, workbooks, physical facilities, etc.;~~

~~—(D) all test questions and corresponding answers; and~~

~~—(E) the radiation safety training, education, and experience of each instructor.~~

~~(k) Issuance of certificate of registration.~~

~~—(1) A certificate of registration application will be approved if the agency determines that an application meets the requirements of the Texas Radiation Control Act (Act) and the requirements of this chapter. The certificate of registration authorizes the proposed activity in such form and contains such conditions and limitations as the agency deems appropriate or necessary.~~

~~—(2) The agency may incorporate in the certificate of registration at the time of issuance, or thereafter by amendment, such additional requirements and conditions with respect to the registrant's possession, use, and transfer of radiation machines subject to this chapter as it deems appropriate or necessary in order to:~~

~~—(A) minimize danger to occupational and public health and safety;~~

~~—(B) require additional reports and the keeping of additional records as may be appropriate or necessary; and~~

~~—(C) prevent loss or theft of radiation machines subject to this section.~~

~~—(3) The agency may request, and the registrant shall provide, additional information after the certificate of registration has been issued to enable the agency to determine whether the certificate of registration should be modified in accordance with subsection (r) of this section.~~

~~(l) Specific terms and conditions of certificates of registration.~~

~~—(1) Each certificate of registration issued in accordance with this section shall be subject to the applicable provisions of the Act, now or hereafter in effect, and to the applicable rules and orders of the agency.~~

~~—(2) No certificate of registration issued or granted under this section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, to any person unless the agency authorizes the transfer in writing.~~

~~—(3) Each person registered by the agency for radiation machine use in accordance with this section shall confine use and possession of the radiation machine registered to the locations and purposes authorized in the certificate of registration.~~

~~—(4) In making a determination whether to grant, deny, amend, renew, revoke, suspend, or restrict a certificate of registration, the agency may consider the technical competence and compliance history of an applicant or holder of a certificate of registration. After an opportunity for a hearing, the agency shall deny an application for a certificate of registration, an amendment to a certificate of registration, or renewal of a certificate of registration if the applicant's compliance history reveals that at least three agency actions have been issued against the applicant, within the previous six years, that assess administrative or civil penalties against the applicant, or that revoke or suspend the certificate of registration.~~

~~(m) Responsibilities of registrant.~~

~~—(1) The registrant shall notify the agency in writing of any changes that would render the information contained in the application for registration and/or the certificate of registration inaccurate.~~

~~—(A) Notification is required within 30 days of the following changes:~~

~~—(i) name and mailing address;~~

~~—(ii) street address where machine will be used;~~

~~—(iii) RSO; or~~

~~—(iv) type of servicing and/or services provided.~~

~~—(B) Each registrant shall inventory all radiation machines in its possession at an interval not to exceed one year. The inventory record shall be maintained for three years for inspection by the agency and shall include:~~

~~—(i) manufacturer's name;~~

~~—(ii) model and serial number of the control panel; and~~

~~—(iii) location of radiation machine(s) (for example, room number).~~

~~—(C) Notification to the agency concerning radiation machine inventory is required within 30 days of either of the following:~~

~~—(i) any change in the category(ies) of machine type or type of use as specified in §289.231(1) of this title and as authorized in the certificate of registration; or~~

~~—(ii) any increase in the number of machines authorized by the certificate of registration in any machine type or type of use category.~~

~~—(D) Each registrant shall maintain records of receipt, transfer, and disposal of radiation machines for inspection by the agency. The records shall include the following information and shall be kept until termination of the certificate of registration:~~

~~—(i) manufacturer's name;~~

~~—(ii) model and serial number from the control panel;~~

~~—(iii) date of the receipt, transfer, and disposal;~~

~~—(iv) name and address of person machine(s) received from, transferred to, or disposed of; and~~

~~—(v) name of the individual recording the information.~~

~~—(2) The following criteria applies to radiation machines used for clinical trial evaluations and loaner or demonstration radiation machines. For persons having a valid certificate of registration, radiation machines used for clinical trial evaluations and loaner or demonstration radiation machines may be used for up to 60 days. After 60 days, the registrant shall notify the agency of the following:~~

~~—(A) a change in the category(ies) of machine type or type of use as specified in §289.231(11) of this title and as authorized in the certificate of registration; or~~

~~—(B) any increase in the number of machines authorized by the certificate of registration in any machine type or type of use category.~~

~~—(3) No registrant shall engage any person for services described in subsection (j) of this section until such person provides to the registrant evidence of registration with the agency.~~

~~—(4) Records of training and experience required by this section shall be maintained for inspection by the agency until disposal is authorized by the agency.~~

~~—(5) The following applies to voluntary or involuntary petitions for bankruptcy.~~

~~—(A) Each registrant shall notify the agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy by the registrant or its parent company. This notification shall include:~~

~~—(i) the bankruptcy court in which the petition for bankruptcy was filed; and~~

~~—(ii) the date of the filing of the petition.~~

~~—(B) A copy of the "petition for bankruptcy" shall be submitted to the agency along with the written notification.~~

~~—(6) The registrant is responsible for complying with this chapter and the conditions of the certificate of registration.~~

~~—(7) No person shall use radiation machines or perform services that are not authorized in the certificate of registration issued by the agency.~~

~~—(8) Providers of equipment shall keep a log of radiation machines provided in Texas. The record shall be maintained for five years for inspection by the agency and shall list the following current information:~~

~~—(A) date machine is provided; and~~

~~—(B) name of customer and customer's certificate of registration number.~~

~~(n) Sale, lease, loan, installation, assembly, disposal, and transfer of radiation machines.~~

~~—(1) No person shall transfer a radiation machine to or install for, other than initial installation of the first machine on the premises, any person who does not possess a current certificate of registration issued by the agency in accordance with this section.~~

~~—(2) Any person who sells, leases, lends, disposes, assembles, installs, or otherwise transfers radiation machines in the state shall notify the agency of the following information within 30 days of such action:~~

~~—(A) the name, address, and certificate of registration number, except in the case of initial machine installation, of persons who have received such machines;~~

~~—(B) the type of radiation machine, the manufacturer's name, model number, and control panel serial number of each radiation machine; and~~

~~—(C) the date of transfer or disposal of each radiation machine.~~

~~—(3) No person shall make, assemble, or install radiation machines or the components of such machines unless such machines and equipment, when properly placed in operation and used, meet the applicable requirements of this chapter.~~

~~(o) Expiration of certificates of registration.~~

~~—(1) Except as provided by subsection (q) of this section, each certificate of registration expires at the end of the day, in the month and year stated in the certificate of registration.~~

~~—(2) If a registrant does not submit an application for renewal of the certificate of registration in accordance with subsection (q) of this section, as applicable, the registrant shall on or before the expiration date specified in the certificate of registration:~~

~~—(A) terminate use of all radiation machines and/or terminate radiation machine servicing or radiation services;~~

~~—(B) submit to the agency a record of the disposition of the radiation machines, if applicable, and if transferred, to whom it was transferred, within 30 days following the expiration date; and~~

~~—(C) pay any outstanding fees in accordance with §289.204 of this title.~~

~~—(3) Expiration of the certificate of registration does not relieve the registrant of the requirements of this chapter.~~

~~(p) Termination of certificates of registration. When a registrant decides to terminate all activities involving radiation machines or services authorized under the certificate of registration, the registrant shall immediately do the following:~~

~~—(1) request termination of the certificate of registration in writing;~~

~~—(2) submit to the agency a record of the disposition of the radiation machines, if applicable; and if transferred, to whom it was transferred; and~~

~~—(3) pay any outstanding fees in accordance with §289.204 of this title.~~

~~(q) Renewal of certificate of registration.~~

~~—(1) An application for renewal of a certificate of registration shall be filed in accordance with subsection (e) of this section and applicable paragraphs of subsections (f) — (j) of this section.~~

~~—(2) If a registrant files an application for a renewal in proper form before the existing certificate of registration expires, such existing certificate of registration shall not expire until the application status has been determined by the agency.~~

~~(r) Modification, suspension, and revocation of certificates of registration.~~

~~—(1) The terms and conditions of all certificates of registration shall be subject to revision or modification. A certificate of registration may be suspended or revoked by reason of amendments to the Act, by reason of rules in this chapter or orders issued by the agency.~~

~~—(2) Any certificate of registration may be revoked, suspended, or modified, in whole or in part, for any of the following:~~

~~—(A) any material false statement in the application or any statement of fact required under provisions of the Act;~~

~~—(B) conditions revealed by such application or statement of fact or any report, record, or inspection, or other means that would warrant the agency to refuse to grant a certificate of registration on an original application;~~

~~—(C) violation of, or failure to observe any of the terms and conditions of the Act, this chapter, the certificate of registration, or order of the agency; or~~

~~—(D) existing conditions that constitute a substantial threat to the public health or safety or the environment.~~

~~(3) Each certificate of registration revoked by the agency ends at the end of the day on the date of the agency's final determination to revoke the certificate of registration, or on the revocation date stated in the determination, or as otherwise provided by the agency order.~~

~~—(4) Except in cases in which the occupational and public health or safety requires otherwise, no certificate of registration shall be suspended or revoked unless, prior to the institution of~~

proceedings therefore, facts or conduct that may warrant such action shall have been called to the attention of the registrant in writing and the registrant shall have been afforded an opportunity to demonstrate compliance with all lawful requirements.

~~(s) Reciprocal recognition of out of state certificates of registration.~~

~~—(1) Whenever any radiation machine is to be brought into the state for any temporary use, the person proposing to bring the machine into the state shall apply for and receive a notice from the agency granting reciprocal recognition prior to beginning operations. The request for reciprocity shall include the following:~~

~~—(A) completed BRC Form 226-1 (Business Information Form);~~

~~—(B) completed BRC Form 252-3 (Notice of Intent to Work in Texas Under Reciprocity);~~

~~—(C) completed qualification forms (BRC Forms 255-E, 255-T and/or 255-OS) for each radiographer who will be working in Texas if the reciprocity request is for industrial radiography;~~

~~—(D) name and Texas licensing board number of the practitioner if the machines are used to irradiate humans;~~

~~—(E) copy of the applicant's current certificate of registration or equivalent document;~~

~~—(F) copy of the applicant's current operating and safety procedures pertinent to the proposed use;~~

~~—(G) fee as specified in §289.204(e) of this title; and~~

~~—(H) qualifications of personnel who will be operating the machines.~~

~~—(2) Upon a determination that the request for reciprocity meets the requirements of the agency, the agency may issue a notice granting reciprocal recognition authorizing the proposed use.~~

~~—(3) Once reciprocity is granted, the out of state registrant shall file a BRC Form 252-3 with the agency prior to each entry into the state. This form shall be filed at least three working days before the radiation machine is to be used in the state. If, for a specific case, the three-day period would impose an undue hardship, the out-of-state registrant may, at the determination of the agency, obtain permission to proceed sooner.~~

~~—(4) When radiation machines are used as authorized under reciprocity, the out of state registrant shall have the following in its possession at all times for inspection by the agency:~~

~~—(A) completed BRC Form 252-3;~~

~~—(B) copy of the notice from the agency granting reciprocity;~~

~~—(C) copy of the out-of-state registrant's operating and safety procedures; and~~

~~—(D) copy of the applicable rules as specified in the notice granting reciprocity.~~

~~—(5) If the state from which the radiation machine is proposed to be brought does not issue certificates of registration or equivalent documents, a certificate of registration shall be obtained from the agency in accordance with the requirements of this section.~~

~~—(6) The agency may withdraw, limit, or qualify its acceptance of any certificate of registration or equivalent document issued by another agency upon determining that such action is necessary in order to prevent undue hazard to occupational and public health and safety or property.~~

~~—(7) Reciprocal recognition will expire one year from the date it is granted. A new request for reciprocity shall be submitted to the agency each year. Reciprocity requests made after the initial request shall include only the following:~~

~~—(A) completed BRC Form 226-1 (Business Information Form);~~

~~—(B) completed BRC Form 252-3 (Notice of Intent to Work in Texas Under Reciprocity);~~

~~—(C) completed qualification forms (BRC Forms 255-E, 255-T and/or 255-OS) for each radiographer who will be working in Texas if the reciprocity request is for industrial radiography;~~
~~—(D) name and Texas licensing board number of the practitioner if the machines are used to irradiate humans;~~
~~—(E) copy of the applicant's current certificate of registration or equivalent document;~~
~~—(F) copy of the applicant's current operating and safety procedures pertinent to the proposed use;~~
~~—(G) fee as specified in §289.204(e) of this title; and~~
~~—(H) qualifications of personnel who will be operating the machines.~~
~~—(8) Radiation services provided by a person from out-of-state will not be granted reciprocity. Whenever radiation services are to be provided by a person from out-of-state, that person shall apply for and receive a certificate of registration from the agency before providing radiation services. The application shall be filed in accordance with subsections (e), (j), and (i) of this section, as applicable.~~

~~(t) Appendices.~~

~~—(1) Requirements for RSOs for registrants.~~

~~—(A) All RSOs shall meet the following general requirements in addition to requirements in specific categories, except for industrial radiography RSOs:~~

~~—(i) knowledge of potential radiation hazards and emergency precautions; and~~

~~—(ii) completed educational courses related to ionizing radiation safety or a radiation safety officer course; or~~

~~—(iii) experience in the use and familiarity of the type of equipment used.~~

~~—(B) Specific requirements for RSOs by facility are as follows.~~

~~—(i) Healing arts facilities shall have:~~

~~—(I) licensed practitioner RSOs with documentation of licensing board number; or~~

~~—(II) non-practitioner RSOs with the following:~~

~~—(a) evidence of a valid general certificate issued under the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter 601, and at least two years of supervised use of radiation machines;~~

~~—(b) evidence of a valid limited general certificate issued under the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter 601, and at least four years of supervised use of radiation machines;~~

~~—(c) evidence of registry by the American Registry of Radiologic Technologists (ARRT) or the American Registry of Clinical Radiologic Technologists (ARCRT) and at least two years of supervised use of radiation machines;~~

~~—(d) evidence of associate degree in radiologic technology, health physics, or nuclear technology, and at least two years of supervised use of radiation machines;~~

~~—(e) evidence of registration with the Board of Nurse Examiners as a Registered Nurse or a Registered Nurse with an extended scope of practice (Nurse Practitioner) performing radiologic procedures, and at least two years of supervised use of radiation machines in the respective practitioners' specialty;~~

~~—(f) evidence of registration with the Texas State Board of Physician Assistant Examiners, and at least two years of supervised use of radiation machines in the respective practitioners' specialty;~~

~~— (g) evidence of:~~

~~— (1) registration with the Texas Medical Board performing radiologic procedures under a physician's instruction and direction;~~

~~— (2) registration with the Texas State Board of Chiropractic Examiners performing radiologic procedures under a chiropractor's instruction and direction; or~~

~~— (3) registration with the Texas State Board of Podiatric Medicine performing radiologic procedures under a podiatrist's instruction and direction; and~~

~~— (4) at least four years of supervised use of radiation machines in the respective practitioners' specialty;~~

~~— (h) for radiotherapy facilities, evidence of registry by the ARRT or ARCRT and at least four years of supervised experience in radiotherapy;~~

~~— (i) evidence of bachelor's (or higher) degree in a natural or physical science, health physics, radiological science, nuclear medicine, or nuclear engineering; or~~

~~— (j) evidence of a current Texas license under the Medical Physics Practice Act, Texas Occupations Code, Chapter 602, in one or more of the following appropriate specialties:~~

~~— (1) medical health physics, diagnostic radiological physics, or medical nuclear physics for diagnostic x-ray facilities; or~~

~~— (2) medical health physics or therapeutic radiological physics for radiotherapy facilities.~~

~~— (ii) Academic institutions and/or research and development facilities shall have RSOs who are faculty or staff members in radiation protection, radiation engineering, or related disciplines. (This individual may also serve as the RSO over the healing arts section of the facility.)~~

~~— (iii) Industrial radiography operations shall have RSOs who meet the requirements of §289.255(m)(4)(B) of this title.~~

~~— (C) Exemptions. The RSO identified on a certificate of registration issued before September 1, 1993, need not comply with the training requirements in this subsection.~~

~~— (2) Responsibilities of RSOs. Specific duties of the RSO include, but are not limited to, the following:~~

~~— (A) establishing and overseeing operating and safety procedures that maintain radiation exposures as low as reasonably achievable (ALARA), and to review them regularly to ensure that the procedures are current and conform with this chapter;~~

~~— (B) ensuring that individual monitoring devices are properly used by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by §289.203 of this title;~~

~~— (C) investigating and reporting to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this chapter and each theft or loss of source(s) of radiation, determining the cause, and taking steps to prevent its recurrence;~~

~~— (D) having a thorough knowledge of management policies and administrative procedures of the registrant and keeping management informed on a periodic basis of the performance of the registrant's radiation protection program, if applicable;~~

~~— (E) assuming control and having the authority to institute corrective actions including shut-down of operations when necessary in emergency situations or unsafe conditions;~~

~~— (F) maintaining records as required by this chapter; and~~

~~— (G) ensuring that personnel are adequately trained and complying with this chapter, the conditions of the certificate of registration, and the operating and safety procedures of the registrant.~~

~~—(3) Minimum education and training for persons performing radiation machine assembly, installation or repair. All persons performing radiation machine assembly, installation or repair shall meet the general requirements in subparagraph (A) of this paragraph and one or more of the specialized requirements in subparagraph (B) of this paragraph.~~

~~—(A) General requirements include:~~

~~—(i) experience or education providing familiarity with the type(s) of equipment to be serviced, to include radiation safety;~~

~~—(ii) knowledge of protective measures to reduce potentially hazardous conditions; and~~

~~—(iii) six months of supervised assembly and repair of the type(s) of equipment to be serviced.~~

~~—(B) Specialized requirements include:~~

~~—(i) one year of formal training (may be satisfied by factory school, military technical training school, or other courses in radiation machine assembly, installation or repair techniques) or an associate's degree in biomedical equipment repair;~~

~~—(ii) a bachelor's degree in electrical engineering with specialized training in radiation producing devices; or~~

~~—(iii) a combination of training and experience equal to clause (i) of this subparagraph.~~

~~—(C) Exemptions. A registrant holding a valid certificate of registration who has hired individuals to perform services before September 1, 1993, need not comply with the education and training requirements in this paragraph. Individuals hired after September 1, 1993, shall comply with the education and training requirements in this paragraph.~~

~~—(4) Information to be submitted by persons proposing to conduct healing arts screening. Persons requesting that the agency approve a healing arts screening program shall submit the following information and evaluation.~~

~~—(A) Administrative controls to include the following:~~

~~—(i) the name and address of the applicant and, where applicable, the names and addresses of agents within Texas;~~

~~—(ii) the diseases or conditions for which the x-ray examinations are to be used in diagnoses;~~

~~—(iii) a detailed description of the x-ray examinations proposed in the screening program;~~

~~—(iv) a description of the population to be examined in the screening program, for example, age, sex, physical condition, and other appropriate information;~~

~~—(v) an evaluation of any known alternate methods not involving ionizing radiation that could achieve the goals of the screening program and why these methods are not used instead of the x-ray examination; and~~

~~—(vi) for mobile screening operations, location(s) where radiation machines are used and maintained.~~

~~—(B) Operating procedures for all x-ray systems (except bone densitometers) to include the following:~~

~~—(i) an evaluation of the x-ray systems to be used in the screening program. The evaluation shall be performed by a licensed medical physicist with a specialty in diagnostic radiological physics. The evaluation shall show that such systems do satisfy all requirements of this section;~~

~~—(ii) a description of the diagnostic imaging quality control program; and~~

~~—(iii) a copy of the technique chart for the x-ray examination procedures to be used.~~

~~—(C) Operating procedures for bone densitometers to include the manufacturer's evaluation of the system to be used in the screening program. The evaluation shall show that such systems satisfy all requirements of this section.~~

~~—(D) Training data to include the following:~~

- ~~—(i) the qualifications of each individual who will be operating the x-ray systems;~~
- ~~—(ii) the qualifications of the individual who will be supervising the operators of the x-ray systems. The extent of supervision and the method of work performance evaluation shall be specified; and~~
- ~~—(iii) the name and address of the practitioner licensed in Texas who will interpret the radiographs.~~
- ~~—(E) Records to include the following:~~
 - ~~—(i) a description of the procedures to be used in advising the individuals screened, and their private practitioners of the healing arts, of the results of the screening procedure and any further medical needs indicated; and~~
 - ~~—(ii) a description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations.~~